

Claims

1. Use of axotrophin or a polypeptide or polynucleotide encoded by or derived from axotrophin to induce or to regulate, directly or indirectly, the immune response of an individual and/or ex vivo cell population to an antigen.
2. Use of axotrophin or a polypeptide or polynucleotide encoded by or derived from axotrophin in the manufacture of a medicament to induce or to regulate, directly or indirectly, the immune response of an individual and/or ex vivo cell population to an antigen.
3. Use according to claim 1 or claim 2 in which the immune response is in a vertebrate wherein the individual has a tissue or cell transplant.
4. Use in the manufacture of a medicament of axotrophin or a polypeptide or polynucleotide encoded by or derived from axotrophin or a substance that alters amount or activity thereof in an individual, to boost or reduce an aggressive immune response against an antigen or to alter tolerance of the immune system to an antigen.
5. Use of axotrophin or a polypeptide or polynucleotide encoded by or derived from axotrophin for assaying immune status.
6. A method of manipulating the response of the immune system to a given antigen in an individual the method comprising administering to the individual axotrophin or a polypeptide or polynucleotide encoded by or derived from axotrophin or a substance that enhances the amount or activity of polypeptide expressed directly or indirectly by axotrophin.
6. A method according to claim 5 comprising potentiating or increasing the aggressive response of the immune system of an individual against an antigen, the method comprising administering to the individual a substance that decreases the amount or activity of a polypeptide expressed directly or indirectly by axotrophin.
7. A method for determining immune status of an individual, the method comprising determining the level of expression of axotrophin or a polypeptide or polynucleotide encoded by or derived from axotrophin in a test sample comprising tissue, cells and/or bodily fluid removed or obtained from the individual and comparing the level for the test sample with that of a control sample, wherein a level in the test sample greater than that of the control sample is indicative that the immune status in the individual comprises a tolerant immune response,

the immune status in the individual comprises an aggressive immune response.

8. Isolated axotrophin, a polynucleotide or a polypeptide encoded by or derived from axotrophin.

9. A method for producing axotrophin polypeptide comprising growing a culture of cells in a culture medium under conditions permitting expression of the axotrophin polypeptide, and purifying the polypeptide from the culture or from the host cells.

10. A vector for the expression of axotrophin, a polynucleotide sequence or a polypeptide encoded by or derived from axotrophin, the vector containing axotrophin or a polynucleotide sequence encoding axotrophin, a promoter sequence and a termination sequence.

11. A composition containing axotrophin or a polypeptide or polynucleotide encoded by or derived from axotrophin and a pharmaceutically acceptable diluent, carrier or excipient.

12. A method of screening chemical compounds comprising contacting a test sample containing one or more chemical compounds to be screened with a binder selected from axotrophin, a polynucleotide or polypeptide encoded by or derived from axotrophin and fragment of such polynucleotide or polypeptide and determining whether the chemical compound has bound to the binder.

13. A method according to claim 12 for identifying an agent which binds to axotrophin or a polypeptide or polynucleotide encoded by or derived from axotrophin comprising:

- (a) contacting an agent with axotrophin or a or polynucleotide polypeptide encoded by or derived from axotrophin;
- (b) determining whether the agent binds to the said polynucleotide or polypeptide; and
- (c) detecting the formation of a complex, formed between the agent and the said polynucleotide or polypeptide such that if a complex is formed, the agent is detected.

14. A method according to claim 13 in which the compound is contacted with axotrophin or polypeptide or polynucleotide of axotrophin in a cell wherein the complex drives expression of a receptor gene sequence in the cell, and detecting the complex by detecting reporter gene sequence expression.

15. A kit comprising:

- i) a polynucleotide or polypeptide probe and/or monoclonal antibodies said probe or antibodies comprising axotrophin or a polypeptide or polynucleotide encoded by or derived from axotrophin; and optionally
- ii) quantitative standards for carrying out method according to any one of the preceding claims.

16. A diagnostic method for detecting axotrophin or a polynucleotide or polypeptide encoded by or derived from axotrophin comprising:

- (a) contacting a sample to be tested for the presence of a polynucleotide or polypeptide encoded by or derived from axotrophin with a compound that binds to a polynucleotide or polypeptide encoded by or derived from axotrophin;
- (b) determining whether the compound binds to a component of the sample; and
- (c) detecting the formation of a complex, formed between the agent and the protein or polynucleotide and such that if a complex is formed, the polypeptide or polynucleotide is detected.

17. A diagnostic method for assessing the immune response of an individual comprising obtaining a test sample from the individual, incubating the test sample with one or more of the antibodies to or polynucleotide probes for axotrophin or a polynucleotide or polypeptide encoded or derived from axotrophin and assaying for binding of the polynucleotide probes or antibodies to a component within the test sample.

18. A method according to claim 16 or claim 17 wherein step (c) comprises testing with an ex vivo immune cell population.

19. A method according to claim 16 or claim 17 wherein step (c) comprises testing in vivo.

20. Use of a compound that binds to a polynucleotide or polypeptide encoded by or derived from axotrophin in the manufacture of a medicament for treating an individual and/or ex vivo cell population to modulate immune response to an antigen.